REMARKS

Specification

The specification has been objected to because of an informality. Appropriate correction has been made. Accordingly, the Applicant respectfully requests withdrawal of the objection to the specification.

Claim Rejections – 35 USC §103

Claims 16 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,083,225 to Winslow et al. ("Winslow") in view of U.S. Patent No. 3,747,603 to Adler ("Adler"). Additionally, claim 18 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Winslow in view of the Adler reference, and in further view of U.S. Patent No. 6,692,502 to Ertl et al., and claim 19 has been rejected in further view of U.S. Patent Application Publication No. 2002/0002360 to Orth et al.

It is well established that "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." MPEP §2142 (citing In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

As an initial matter, the Applicant is unclear as to the basis of the rejections set forth in the Office Action. At the top of page 3 of the Office Action, claims 16 and 17 were rejected as being unpatentable over U.S. Patent No. 6,083,225 to Winslow et al. in view of U.S. Patent No. 3,747,603 to Adler. Similarly, at the bottom of page 3, claims 16-18 were rejected as being unpatentable over U.S. Patent No. 6,083,225 to Winslow et al. in view of U.S. Patent No. 3,747,603 to Adler, and in further view of U.S. Patent No. 6,692,502 to Ertl et al. However, in the paragraphs that follow, references are made to "Gravlee et al.". Accordingly, the Applicant

is unsure as the particular grounds of the claim rejections. Clarification as to the basis of the claim rejections set forth in the Office Action is respectfully requested.

Independent Claim 16 and Dependent Claims 17-19

Claims 16 and 17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,083,225 to Winslow et al. in view of U.S. Patent No. 3,747,603 to Adler.

The Applicant has amended independent claim 16 to recite a surgical kit which includes at least one intervertebral disc spacer configured for insertion into an intervertebral disc space to maintain the intervertebral disc space at a desired height, at least one guide needle, a plurality of dilators sized and configured to incrementally increase a height of the intervertebral disc space and each having an inner diameter successively larger than an outer diameter of a previous dilator such that a distal end portion of each dilator is positioned within the intervertebral disc space to incrementally increase a height of the intervertebral disc space, and a package including a top cover and a bottom cover forming packaging for containing the recited components in a sterilized condition.

With regard to the rejection independent claim 16 as being unpatentable over Winslow in view of Adler, the Office Action asserts that Winslow discloses the claimed invention except for at least one guide needle and a plurality of dilators. However, the Office Action further asserts that Gravlee et al. discloses at least one guide needle and a plurality of dilators, and that it would have been obvious to one skilled in the art to provide a kit including the spinal implant disclosed in Winslow with the components disclosed in Gravlee to arrive at the claimed invention. The Applicant respectfully disagrees with this assertion for at least the following reasons.

Winslow discloses a fusion cage 200 which is inserted into an intervertebral disc space via a retractor instrument 10 including an axial sleeve 12 and a pair of retractor arms or tangs 20 extending from the sleeve 12. As set forth in column 9, lines 31-34 and Figure 11 of Winslow, "[u]pon insertion of retractor arms 20, the vertebral bodies V_1, V_2 are distracted whereby the retractor arms 20 become firmly lodged within the intervertebral space." The fusion cage 200 is thereafter inserted through the sleeve 12 and into the intervertebral space. With regard to Adler, the Applicant notes that this reference fails to disclose or suggest a plurality of dilators that each

have an inner diameter successively larger than an outer diameter of a previous dilator. Instead, as illustrated in Figures 1-9 and as described in the specification, Adler discloses the use of dilators having solid probes shaft 12, and fails to disclose or even suggest the use of a plurality of tubular dilators that each have an inner diameter successively larger than an outer diameter of a previous dilator.

With regard to Gravlee, albeit this reference does appear to disclose a plurality of dilators that are sequentially inserted over one another to dilate a passage, Gravlee clearly and unambiguously discloses that the dilators 14 are used to dilate soft, stretchable tissue to increase the size of a passage through the soft tissue. Indeed, as illustrated in Figure 2 and as set forth in the specification, the dilators are used "to dilate stretchable tissue" such as the cervical canal or the urinary tract (see column 1, lines 10-16 and 36-39; column 4, lines 4-7) or "body orifices, ducts or wounds" (column 2, lines 39-43). However, there is no indication or suggestion whatsoever that the dilators 14 are sized and configured to incrementally increase a height of the intervertebral disc space via positioning of a distal end portion of each dilator within the intervertebral disc space, as recited in independent claim 16. To the contrary, the dilators 14 are used to dilate soft, stretchable tissue, and not to distract rigid vertebral bodies to incrementally increase a height of an intervertebral disc space. Furthermore, the dilators 14 are specifically disclosed as being fabricated from a flexible material such as a polymer to avoid trauma or injury to soft tissue. (Column 3, lines 44-47). However, the plurality of dilators recited in independent claim 16 are sized and configured to act against bony structures (i.e., vertebral bodies) to incrementally increase a height of the intervertebral disc space, thereby requiring a dilator formed of a much harder and rigid material compared to the flexible dilators 14 disclosed in Gravlee. The flexibility and softness of the dilators 14 would prohibit use of these components to distract an intervertebral disc space where much more rigid anatomical features are encountered.

For the reasons set forth above, the cited references of record fail to disclose each of the elements and features recited in independent claim 16, either expressly or inherently. Accordingly, withdrawal of the rejection of independent claim 16 is respectfully requested.

Additionally, contrary to the assertion set forth on page 3 of the Office Action, the Applicant submits that it would not have been obvious to one skilled in the art to provide a kit including the spinal implant disclosed in Winslow with the components disclosed in Gravlee to arrive at the claimed invention. As indicated above, the Winslow reference discloses a retractor instrument 10 that is specifically configured to distract an intervertebral space via insertion of the retractor arms or tangs 20 into the intervertebral space. Since Winslow already discloses a specific type of instrument to distract the disc space, one skilled in the art would not provide additional instrumentation to sequentially distract the intervertebral disc, such as the flexible dilators 14 disclosed in Gravlee or the plurality of dilators recited in independent claim 16. Indeed, the addition of such instrumentation would be duplicative, unnecessary, and would result in increased cost. Accordingly, one skilled in the art would be dissuaded from combining a plurality of dilators with the spinal implant 200 and the distractor instrument 10 disclosed in Winslow to provide the surgical kit recited in independent claim 16.

Furthermore, one skilled in the art would not be motivated to combine the flexible dilators disclosed in Gravlee with a spinal implant configured for insertion into an intervertebral disc space to maintain the intervertebral disc space at a desired height, as recited in independent claim 16. As discussed at length above, Gravlee discloses flexible dilators 14 that are used to dilate soft, stretchable tissue, including the soft tissue surrounding the cervical canal or the urinary tract. The Applicant submits that one skilled in the art would not combine instrumentation configured to dilate soft, stretchable tissue with a spinal implant configured for insertion between intervertebral bodies to maintain an intervertebral disc space at a desired height, much less to combine these components within a surgical kit.

Additionally, the Applicant notes that independent claim 16 does not merely recite a combination of components, but more specifically recites a combination of components that are packaged in a surgical kit. However, neither Winslow nor Gravlee disclose or suggest the concept of packaging the individual components disclosed therein in a self-contained surgical kit including an intervertebral disc spacer, a guide needle, and a plurality of dilators, as recited in independent claim 16. The surgical kit recited in independent claim 16 includes instrumentation to perform the designated surgical procedure of percutaneous interbody fusion, with the

necessary components contained within a common package in a sterilized condition. None of the references of record disclose the concept of providing the recited components within common packaging in a self-contained surgical kit. Additionally, while the Orth reference appears to disclose a kit, the Orth reference does not disclose or suggest packaging of the specific components recited in independent claim 16 is a surgical kit.

Moreover, the Office Action indicates "that all of the components of the claimed invention can inherently be assembled into a kit." (See page 4). However, in order for an element to be inherently disclosed, it must "necessarily be present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." In re Robertson , 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citing Continental Can Co. v. Monsanto Co., 948 F2d 1264, 1268 (Fed. Cir. 1991)). However, inherency "may not be established by probabilities or possibilities . . . The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Id. at 1951. Additionally, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (USPTO Bd. of Pat. App. and Interferences 1990) (emphasis in the original). It is respectfully submitted that packaging each of the components recited in independent claim 16 in a self-contained surgical kit is not disclosed in the cited references so as to "necessarily be present in the thing described in the reference", and likewise does not necessarily flow from the teachings of the cited references. Additionally, the Office Action has not provided any basis in fact and/or technical reasoning supporting the inherency of packaging each of the components recited in independent claim 16 in a self-contained surgical kit. Consequently, the surgical kit recited in independent claim 16 is not disclosed, inherently or otherwise, by the cited references. Accordingly, a *prima facie* case of obviousness has not been established with regard to independent claim 16 for this additional reason as well.

For the reasons set forth above, independent claim 16 is submitted to be patentable over the combination of Winslow, Gravlee, and any of the other references of record. Accordingly,

withdrawal of the rejection of independent claim 16 and allowance of the same are respectfully requested.

Moreover, each of claims 17-19 depends either directly or indirectly from independent claim 16 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 16. Additionally, further reasons support the patentability of these claims. For example, claim 17 further recites that the surgical kit includes a tool for delivering the disc spacer into through one of the dilators and into the intervertebral space, and claim 18 further recites that the surgical kit includes a bone matrix material. However, none of the references of record discloses or suggests the concept of packaging these additional elements and components within the self-contained surgical kit recited in independent claim 16.

New Independent Claim 21 and Dependent Claims 22-33

Independent claim 21 and dependent claims 22-33 have been added to the subject application. Independent claim 21 is directed to a surgical kit including, among other elements and features, a spinal implant configured for insertion into an intervertebral disc space to maintain the intervertebral disc space at a desired height, and a plurality of dilators sized and configured to incrementally increase a height of the intervertebral disc space, including a first dilator having an outer diameter and a distal end portion sized for insertion into the intervertebral disc space, and a second dilator having an inner diameter sized larger than an outer diameter of the first dilator to allow passage of the second dilator over the first dilator until a distal end portion of the second dilator is positioned within the intervertebral disc space to incrementally increase a height of the intervertebral disc space. Support for independent claim 21 may be found, for example, on page 8, line 8 to page 9, line 7, on page 9, line 22 to page 10, line 5, and in Figures 5, 6 and 8 of the as-filed application.

As discussed above with regard to independent claim 16, Gravlee discloses that the dilators 14 are used to dilate soft, stretchable tissue to increase the size of a passage through the soft tissue, and fails to provide any indication or suggestion whatsoever that the dilators 14 are sized and configured to incrementally increase a height of an intervertebral disc space, as recited in independent claim 21. To the contrary, the dilators 14 are used to dilate soft, stretchable

tissue, and not to distract rigid vertebral bodies to incrementally increase a height of an intervertebral disc space. Additionally, the dilators 14 are specifically disclosed as being fabricated from a flexible material such as a polymer to avoid trauma or injury to soft tissue, which would prohibit use of these components to distract an intervertebral disc space where much more rigid anatomical features are encountered. Moreover, as also indicated above with regard to independent claim 16, since Winslow already discloses a specific type of instrument to distract the disc space, one skilled in the art would not provide additional instrumentation to sequentially distract the intervertebral disc, such as the flexible dilators 14 disclosed in Gravlee or the plurality of dilators recited in independent claim 21. Furthermore, one skilled in the art would not be motivated to combine the flexible dilators disclosed in Gravlee with a spinal implant configured for insertion into an intervertebral disc space to maintain the intervertebral disc space at a desired height, as recited in independent claim 21. Indeed, Gravlee discloses flexible dilators 14 that are used to dilate soft, stretchable tissue, including the soft tissue surrounding the cervical canal or the urinary tract. One skilled in the art would not combine instrumentation configured to dilate soft, stretchable tissue with a spinal implant configured for insertion between intervertebral bodies to maintain an intervertebral disc space at a desired height, much less to combine these components within a surgical kit. The Applicant further notes that independent claim 21 does not merely recite a combination of components, but more specifically recites a combination of components that are provided in a self-contained surgical kit. However, neither Winslow nor Gravlee disclose or suggest the concept of providing the individual components disclosed therein in a self-contained surgical kit including a spinal implant configured to maintain an intervertebral disc space at a desired height, and a plurality of dilators sized and configured to incrementally increase a height of the intervertebral disc space, as recited in independent claim 21.

For at least these reasons, allowance of independent claim 21 is respectfully requested. Moreover, claims 22-33 depend either directly or indirectly from independent claim 21 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 21.

New Independent Claim 34 and Dependent Claims 35 and 36

Independent claim 34 has also been added with this response. Independent claim 36 is directed to a surgical kit and recites, among other elements and features, at least one spinal implant configured for insertion into the intervertebral disc space to maintain the intervertebral disc space at a desired height, a plurality of dilators sized and configured to incrementally increase a height of the intervertebral disc space and including a first dilator having an outer diameter and a distal end portion sized for insertion into the intervertebral disc space, a second dilator having an inner diameter sized larger than an outer diameter of the first dilator to allow passage of the second dilator over the first dilator until a distal end portion of the second dilator is positioned within the intervertebral disc space to incrementally increase a height of the intervertebral disc space, and a third dilator having an inner diameter sized larger than an outer diameter of the second dilator to allow passage of the third dilator over the second dilator until a distal end portion of the third dilator is positioned within the intervertebral disc space to incrementally increase the height of the intervertebral disc space, and packaging which contains and maintains the at least one spinal implant and the plurality of dilators in a sterilized condition. Support for independent claim 34 may be found, for example, on page 8, line 8 to page 9, line 7, on page 9, line 22 to page 10, line 5, and in Figures 5, 6 and 8 of the as-filed application.

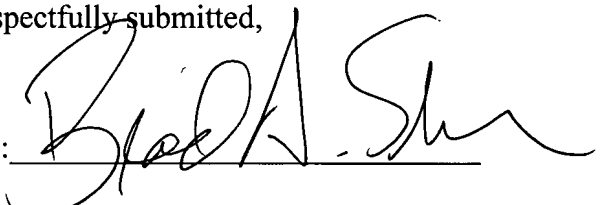
Independent claim 34 is submitted to be patentable over the cited references for reasons similar to those discussed above with regard to independent claims 16 and 21. Accordingly, allowance of independent claim 34 is respectfully requested. Moreover, claims 35 and 36 depend either directly or indirectly from independent claim 34 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 34.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 16-19 and 21-36.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

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